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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/826,206	04/05/2001	John D' Elia	030918	2584

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EXAMINER

RAO, MANJUNATH N

ART UNIT	PAPER NUMBER
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1652

DATE MAILED: 03/15/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/826,206

Applicant(s)

D' ELIA, JOHN

Examiner

Manjunath N. Rao, Ph.D.

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 03 January 2005.
2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1,5-14,17-39 and 44-56 is/are pending in the application.
4a) Of the above claim(s) _____ is/are withdrawn from consideration.
5) ☐ Claim(s) _____ is/are allowed.
6) ☒ Claim(s) 1,5-14,17-39 and 44-56 is/are rejected.
7) ☐ Claim(s) _____ is/are objected to.
8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

CONTINUED EXAMINATION UNDER 37 CFR 1.114 AFTER FINAL REJECTION

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 1-3-05 has been entered.

Claims 1, 5-14, 17-39, 44-56 are currently pending and are present for examination.

Applicants' amendments and arguments filed on 1-3-05, have been fully considered and are deemed to be persuasive to overcome the rejections previously applied. Rejections and/or objections not reiterated from previous office actions are hereby withdrawn. Specifically, Examiner has withdrawn the previous rejections held under 35 U.S.C. 112, 1st paragraph in view of claim amendments which overcome said rejections.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claim 48 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Claim 48 recites the phrase "sequences at least 95% identical to nucleotides 2955-2960 of SEQ ID NO:2" twice in lines 2, 3, 4 which makes no scientific sense. It is not clear as to how the function of a "replicon" can be attributed to a stretch of just 6 nucleotides. Examiner

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requests clarification and support in the specification for the above phrase from the applicant.

Furthermore the claim also recites the phrase "wherein the nucleic acid comprises" in line 2 which is also not clear to the Examiner. It is not clear whether applicant means "nucleic acid molecule". Examiner urges applicant to recite "polynucleotide" in place of nucleic acid or nucleic molecule for clarity.

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 1, 5-14, 17-39, 44-56 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-25 of U.S. Patent No. 6,503,748. An obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but an examined application claim is not patentably distinct from the reference claim, because the examined claim is either anticipated by, or would have been obvious over the reference claim. See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi* 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985). Although the conflicting claims are not identical, they

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are not patentably distinct from each other. Claims 1, 5-14, 17-39, 44-56 of the instant application and claims 1-25 of the reference patent are both directed to nucleic acid molecules comprising a polynucleotide sequence of an endogenous plasmid contained in NRRL deposit No.B-30035 and vectors and host cells comprising said nucleic acid molecule. Among the nucleic acid molecules, vectors and host cells claimed in the instant application and in the reference patent a good number of nucleic acid molecules (sequence stretches) are identical to one another. The portion of the specification (and the claims) in the reference patent that supports the recited nucleic acid molecules includes embodiments (for example, claim 1 drawn to an isolated nucleic acid molecule comprising a polynucleotide having a nucleotide sequence at least 95% identical to a nucleotide sequence in SEQ ID NO:1) that would anticipate the claimed nucleic acid molecules in claims 1, 5-14, 17-39, 44-56 herein. Claims of the instant application listed above cannot be considered patentably distinct over claims 1-25 of the reference patent when there is specifically recited embodiment that would anticipate claims 1, 5-14, 17-39, 44-56 of the instant application. Alternatively, claims 1, 5-14, 17-39, 44-56 cannot be considered patentably distinct over claims 1-25 of the reference patent when there is specifically disclosed embodiment in the reference patent that supports claims 1-25 of that patent and falls within the scope of claims 1, 5-14, 17-39, 44-56 herein because it would have been obvious to one having ordinary skill in the art to modify claims 1-25 of the reference by selecting a specifically disclosed embodiment that supports those claims i.e., for example, it would have been obvious to those skilled in the art to select the plasmid of NRRL deposit No. B-30035 or those that hybridize thereto. Each of these polynucleotides anticipate the claims of the instant application.

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One of ordinary skill in the art would have been motivated to do this because that embodiment is disclosed as being a preferred embodiment within claims 1-25 of the reference patent.

In response to one of the previous Office action, applicant had indicated that a T.D. will be filed upon indication of allowable subject matter. However, in the recent amendment filed, applicant continues to argue that a double patenting issue does not exist. Examiner thanks the applicant for the graphical representation. It can be readily seen from said graphics that indeed all the polynucleotides claimed in the instant application are derived from the polynucleotide of the issued patent. Therefore examiner reiterates that claim 1 of the instant application is drawn to an isolated or purified nucleic acid molecule comprising a *Ketogulonigenium* plasmid replicon as shown in SEQ ID NO:1 which is also the same as the claimed polynucleotide in claim 1 of the issued patent. The polynucleotide claimed in claim 1 of the issued patent does comprise SEQ ID NO:1 of the instant application and the function of said polynucleotide is inherent in it(replicon). Therefore limitations of the instant claim 1 is encompassed in the claim 1 of the patent. Furthermore, applicant's argument that SEQ ID NO:1, 3 and 4 of the instant application are different from SEQ ID NO:1 of the issued patent is highly misplaced. This is because claims 2, 3 and 4 of the instant application all recite "comprising" language and even if applicant amended these claims to recite "consisting of" language, said claims would continue to be obvious over claim 1 of the issued patent. Therefore, contrary to applicant's argument, Examiner reiterates that the Double patenting issue exists and maintains the Double Patenting rejection.

Conclusion

None of the claims are allowable.

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Any inquiry concerning this communication or earlier communications from the Examiner should be directed to Manjunath N. Rao, Ph.D. whose telephone number is 571-272-0939. The Examiner can normally be reached on 7.00 a.m. to 3.30 p.m. If attempts to reach the examiner by telephone are unsuccessful, the Examiner's supervisor, Ponnathapura Achutamurthy can be reached on 571-272-0928. The fax phone numbers for the organization where this application or proceeding is assigned is 571-273-8300 for regular communications and for After Final communications. Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 571-272-1600.



Manjunath N. Rao, Ph.D.
Primary Examiner
Art Unit 1652

March 10, 2005